PHARMACEUTICAL ADVERTISING ADVISORY BOARD JANUARY 2011

PAAB REVIEW

Year 2011 marks the 34th year of the PAAB since its incorporation in 1976. To see the current edition of the PAAB Code, visit the PAAB Web-site.

www.paab.ca

Ce document est également disponible en français sur notre site web.

PAAB MEETINGS

March 8, 2011 – Executive Committee Meeting

April 15, 2011 – Annual/General Meeting

MISSION, VISION, VALUES

MISSION: To provide a preclearance review that fosters trustworthy healthcare communications within the regulatory framework.

VISION: Trusted healthcare product communication that promotes optimal health.

VALUES: Integrity, Competency, Credibility, Independence, Excellence, Transparency

EDITORIAL ADVERTISING

Several sources have brought a marketing activity to the attention of the PAAB commissioner. It is sponsored editorials. This type of advertising is covered in section 7.6 Editorial Advertising of the "PAAB Code of Advertising Acceptance". Commissioner Chepesiuk sought the opinion of Health Canada on a number of these published articles. HC agreed on 8 of them that they were likely advertising. Monitoring notices were sent to companies advising them of the Food & Drugs Act, and the PAAB Code requirement for preclearance review of advertising. If you have any questions about marketing activities being presented to you, you can ask the PAAB Chief Review Officer, Patrick Massad. In 2011 the PAAB will be sending enforcement letters to companies who wish to carry on this activity after our warnings.

EN-NHPS

The board agreed unanimously that the PAAB should not review EN-NHPs because the product claims had not been reviewed and approved by Health Canada and there was no certainty that the claims would be based on solid evidence. That could compromise the accuracy of the PAAB review process. We note that the Health Canada regulation has a sunset clause 30 months after implementation.

CLIENTS INVITATION

The PAAB commissioner is proud of the high level of customer service shown by the PAAB staff. We strive for continuous quality improvement. We remind you that the door to the commissioner's office is open to receive comments about PAAB activities or review issues. We would like to receive specific examples that caused satisfaction or dissatisfaction for the client to help identify trends for areas of improvement of the PAAB review service. Our Customer Experience surveys have not revealed negative comments that we were able to act on. We would like to document and investigate specific cases and take appropriate action. You can contact the commissioner at 905-509-2275 x28 and by email at commish@paab.ca.

COMPANY CONTROLLED PATIENT INFORMATION:

CLARIFICATION REGARDING PAAB CODE SECTION 6.4.3.

The PAAB has increasingly been receiving preclearance submissions that include health care professional (HCP) fair balance in patient directed

APS. Although this may be appropriate for portions of an APS which are intended to remain with the physician, it is not appropriate for any material provided to the patient. All messaging directed towards patients should be consistent with part III of the product monograph (i.e. the "Consumer Information" section) and worded in a manner which is easily understood by the intended audience.

Parts I and II of the product monograph are developed for HCPs and not intended for patients. HCP fair balance often contains types of content which should not appear in a patient directed piece (e.g. most common adverse events incidences from part I of the PM).

When product branded patient information is intended to be distributed to patients through HCPs, please instruct your drug representatives to leave a product monograph (or PAAB approved product information s7.3) for HCP use.

Hybrid APS containing both patient and HCP directed messaging (e.g. teaching easels) may require separate sets of fair balance geared towards each audience. Please note that for such hybrid APS, all HCP messaging and the patient messaging need to be separate and distinct from each other. The key principle to consider is that patients should be able to under stand "patient information".

PRODUCT INFORMATION (PI)

The PAAB Directors have approved in principle the possibility to change the PAAB Code requirement for Product Information that accompanies advertising. The change would allow a link to the PI in the ad. The PAAB will examine how the code can be changed to accommodate this new format. Any changes will have to be within the current federal regulatory framework and the opinion of Health Canada will be sought.

RESEARCH FUNDS

If you are a bona fide researcher and you are aware of any pressing need for data to help answer questions about pharmaceutical advertising, please call Commissioner Chepesiuk at the PAAB office to discuss possible funding. The PAAB directors will make final decisions.

TRAINING WORKSHOPS

The PAAB, in conjunction with Pharmahorizons, conducts ad hoc training sessions at the request of pharma/biotech companies, agencies and suppliers. Check the PAAB web-site for details.

The next national open workshops will be held February 16, 2011 in Montreal and February 18, 2011 in Toronto. CRO Patrick Massad and Reviewer Jennifer Carroll will be faculty along with facilitator Steve Gregory. Check the PAAB web-site under "What's New" for registration details through Pharmahorizons.

CUSTOMER EXPERIENCE INDEX

The PAAB's primary role is to ensure that advertising of prescription drugs is accurate, balanced and evidence based. The PAAB staff strives to provide service that is accurate, transparent and prompt, demonstrating a high level of scientific and regulatory expertise in its reviews.

In late May, 2008, we introduced a Customer Experience Index Survey (CEI). This will provide the PAAB with a systematic and ongoing tool for client feedback, measuring administration, reviewers, management, general process and technology.

Clients who have had an APS accepted will be randomly selected to receive a survey involving 14 questions. If you get one, please complete it and send it back to us promptly. It is important to answer the questions regarding the referenced review file. It is the commitment of the PAAB to improve our customer service. Results for 2010 indicate a continuance of an 80% satisfaction level with the individual file that the client commented on. The

PAAB commissioner is pleased with the results and is encouraging the staff to keep up the good work.

SOCIAL MEDIA MARKETING

Commissioner Chepesiuk has accepted an invitation to be a faculty member at the E-Pharma Summit in New York City in February 2010 as well as a speaker at the E-Marketing Europe 2011 conference in Munich Germany in March 2011. CRO Patrick Massad and Commissioner Chepesiuk will appear as speakers in a Canadian E-Marketing meeting to be held in Toronto March 21-23, 2011. See y'all there.

REVIEW ACTIVITY

During the period of September 1 to December 31, 2010, the total number of first review submissions was 1705 with 10 files going more than 10 days on first review. This compared to 1451 during the same period of 2009. The total for the year to date is 6132 with 33 (0.5%) files going more than 10 days on first review compared to 5168 in 2009. The reviewers averaged 6.5 days for turnaround to first review.

To address industry perception, the PAAB can now generate a report to show how long the client holds a file vs. the PAAB during the review process to acceptance. In 2010, on average the PAAB has held the file 3.4 days vs. the client holding it 11.2 days. In 2009 the PAAB held it for 4.2 days on average of all accepted files vs. 15 days by the client. The overall process appeared to be more efficient this year.

The average number of total revisions per submission for a file by agency was 2.5 in 2010 (2.7 in 2009). Ask CRO Patrick Massad how your agency or company fared in 2010.

USE OF PAAB LOGO

We encourage you to show the PAAB logo on all material reviewed to acceptance (HP) or to no objection (DTC). The new DTC codes are CA for advertising and CI for information. The clearance period is for 12 months and please submit a renewal request if you wish to use the advertising for longer than 12 months. Two month extensions for exceptional circumstances can be granted by the commissioner.

PAAB COMPLAINT REPORT

During the period of September 1 to December 31, 2010, the PAAB Commissioner processed 1 Stage 2 complaint.

In addition, PAAB has continued to regularly monitor journals, the Internet, and receive direct-mail/detail aid materials collected by health professionals as part of its monitoring program. When Code violations are discovered, PAAB sends a letter to the advertiser seeking their cooperation to meet the requirements of the Code. When appropriate, PAAB will notify the advertiser's trade association and/or Health Canada for their assessment of additional penalties. In the last quarter of 2010 the PAAB sent 10 monitoring notices, 8 of which involved alleged paid editorial articles sponsored by pharma companies that were deemed to be advertising.

STAGE TWO DECISIONS

1. **ADVERTISER**: Pfizer

COMPLAINANT: McNeil Consumer

SUBJECT: c10-28 Champix various APS

PRECLEARANCE: Yes

ALLEGATIONS: Claim of 1.7x more effective than NRT patch was not based on good evidence.

DECISION: The approved claim in question had been based on an open-label study with smoking cessation as an objective endpoint and had been used for two years in the marketplace. The author stated it was consistent with other evidence. Since the study results had not been corroborated by double-dummy well controlled studies and it could be argued that smoking cessation was a multi-factorial process, it was decided that the one open-label study was not sufficient evidence for such a claim.

OUTCOME: Waiting response from Pfizer.

For information or if you have comments:

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